



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1119]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions of reporting and recordkeeping requirements for firms that process acidified foods and thermally processed low-acid foods in hermetically sealed containers, and provides notice of and invites comments on our proposed revisions to the electronic submission system and paper-based forms for this collection.

DATES: Submit either electronic or written comments concerning the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2)

the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers--21 CFR 108.25 and 108.35, and Parts 113 and 114 (OMB Control Number 0910-0037)--Revision

Section 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance which may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially Clostridium botulinum. The spores of C. botulinum need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c) (21 CFR 113.89, 114.89, and 114.100(c))); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (21 CFR 113.60(c) (thermally processed foods) and 114.80(b) (21 CFR 114.80(b) (acidified foods))).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

As described in our regulations, processors may obtain the paper versions of Forms FDA 2541, FDA 2541a, and FDA 2541c by contacting us at a particular address. Processors mail completed paper forms to us. However, processors who are subject to § 108.25, 108.35, or both, have an option to submit Forms FDA 2541, FDA 2541a, and FDA 2541c electronically (Ref. 1) (see also 76 FR 11783 at 11785; March 3, 2011).

In this document, we are providing notice that we are updating the process filing portion of the electronic submission system to incorporate “smart form” technology. The updated process filing portion of the electronic submission system will query the processor about the processes used to produce the food and present only those data entry fields that are applicable. This will reduce the burden on processors and reduce errors in process filing because processors will no longer need to evaluate whether particular data entry fields are applicable to their products. For example, when a processor submits a process filing for a product that is processed using a low-acid retorted method with a process mode of “agitating”, “smart form” technology would bypass questions that are not applicable to this process mode option.

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we will continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are proposing to eliminate Forms FDA

2541a (Ref. 2) and FDA 2541c (Ref. 3) and replace these two forms with a total of four forms. Each of the four proposed replacement forms will pertain to a specific type of commercial processing and will be available both on the electronic submission system and as a paper-based form. The electronic submission system and the paper-based form will “mirror” each other to the extent practicable. The four proposed replacement process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method) (Ref.4);
- Form FDA 2541e (Food Process Filing for Acidified Method) (Ref. 5);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method) (Ref. 6); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems) (Ref. 7).

Some of the data entry fields on the four proposed replacement process filing forms are not on current Forms FDA 2541a and FDA 2541c. We added certain data entry fields to improve the efficiency of our review of the process filings. For example, the four proposed replacement forms include data entry fields for the “food product group” (such as liquid, ready-to-eat “breakfast foods”). We estimate that any time it would take to provide such information not already on Form FDA 2541a or FDA 2541c would be offset by the time processors will save by not having to evaluate whether certain data entry fields on Form FDA 2541a or FDA 2541c are applicable to their products. At this time, the paper-based versions of the four proposed replacement forms and their instructions are all available for review as references to this document (Refs. 4 through 11) or at

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm>. After we review the comments received in response to this notice, we will determine what, if any, changes will be made to the paper-based versions of the forms. We

will then complete the development of the electronic submission system to mirror the revised paper forms. The draft electronic versions of the forms will be made available for review on OMB's Web site when we publish a second notice in the Federal Register announcing the submission of the information collection request to OMB. That notice will have a 30-day public comment period.

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹						
21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 108.25(c)(1) and 108.35(c)(2); Food canning establishment registration	2541	645	1	645	0.17 (10 mins.)	110
§ 108.25(c)(2); Food process filing for acidified method	2541e	726	11	7,986	0.333 (20 mins.)	2,659
§ 108.35(c)(2); Food process filing for low-acid retorted method	2541d	336	12	4,032	0.333 (20 mins.)	1,343
§ 108.35(c)(2); Food process filing for water activity/formulation control method	2541f	37	6	222	0.333 (20 mins.)	74
§ 108.35(c)(2); Food process filing for low-acid aseptic systems	2541g	42	22	924	0.75 (45 mins.)	693
§§ 108.25(d) and 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce	N/A	1	1	1	4	4
Total						4,883

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of the number of respondents in table 1 on registrations, process filings, and reports received over the past 3 years. The hours per response reporting estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

Table 2.--Estimated Annual Recordkeeping Burden ¹					
21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
108, 113, and 114	10,392	1	10,392	250	2,598,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double-counting, we have not included estimates for §§ 108.25(g), 108.35(c)(2)(ii), and 108.35(h) because they merely cross-reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the

third party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. No burden has been estimated for the third party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

II. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.)

1. FDA 2012. "Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format". Available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.htm>.

2. Form FDA 2541a. Food Process Filing for All Methods Except Low-Acid Aseptic. Available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076784.pdf>.

3. Form FDA 2541c. Food Process Filing for Low-Acid Aseptic Systems. Available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM123687.pdf>.

4. Draft Form 2541d. Food Process Filing for Low-Acid Retorted Method. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365066.pdf>.

5. Draft Form 2541e. Food Process Filing for Acidified Method. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365058.pdf>.

6. Draft Form 2541f. Food Process Filing for Water Activity/Formulation Control Method. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365059.pdf>.

7. Draft Form 2541g. Food Process Filing for Low-Acid Aseptic Systems. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365060.pdf>.

8. Draft Instructions for Paper Submission of Form FDA 2541d. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366881.pdf>.

9. Draft Instructions for Paper Submission of Form FDA 2541e. Available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366882.pdf>.

10. Draft Instructions for Paper Submission of Form FDA 2541f. Available at
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366884.pdf>

11. Draft Instructions for Paper Submission of Form FDA 2541g. Available at
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366885.pdf>.

Dated: September 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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